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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	16

DATE MAILED: 09/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/000,004	Applicant(s) TSILIBARY ET AL.	
	Examiner Sally A Sakelaris	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-56* is/are pending in the application.

4a) Of the above claim(s) *1-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *31-56* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Lack of Unity

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention(as represented by the groups listed below) to which the claims must be restricted.

Group I, claims 31-42 and 45-47 and 48-56, are drawn to a method for identifying a mammal with and without diabetes that has, or is at risk for developing glomerulonephropathy through polynucleotide analysis and kits containing primers and probes.

Group II, claims 31-34, 43-48, and 52, are drawn to a method for identifying a mammal without diabetes that has or is at risk for developing glomerulonephropathy through detection of integrin proteins with antibodies and a kit containing antibodies.

2. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

It is noted that each of the present claims has been presented in improper Markush format, as distinct methods are improperly joined in the claims. With respect to the methods of Groups I and II, each one consists of analysis with an unique biomolecule, differing in their structural and functional properties. Additionally, the method claims of Groups I and II are distinct from the other in that each biomolecule being analysed in the method comprises a distinct structure and as a whole each biomolecule is functionally distinct over each other. Each

method has a different special technical feature. As the claimed methods using both analysis with polynucleotides and antibodies do not share a special technical feature, the distinct methods may not properly be presented in the alternative. Accordingly, the claims have been separated into a number of groups corresponding to the number of different inventions encompassed by the claims, and the claims will be searched only as they read upon the elected invention from the methods of Groups I and II that require different analyses using either polynucleotides or antibodies.

Further, the claimed methods of Groups I and II have different objectives, require different process steps and require the use of different reagents. The method of Group I requires the steps of identifying a mammal with and without diabetes that has, or is at risk for developing glomerulonephropathy through polynucleotide analysis and kits containing primers and probes. The method of Group II requires the steps of identifying a mammal without diabetes that has or is at risk for developing glomerulonephropathy through antibody analysis and a kit containing antibodies. While Group I is directed to a method utilizing nucleic acids as a reagent, composed of phosphodiester linked nucleotides, Group II is directed to a method utilizing antibodies as reagents, composed of amino acids linked by peptides bonds and glycosylated with an unique tertiary structure. The nucleic acid and antibody require different method steps to accomidate their variant physical characteristics. In addition to differences in objectives, effects, and method steps, it is again noted that the method claims of the present Groups are not directed to the detection or identification of molecules having the same or common special technical feature, for the reasons discussed above.

Restriction Requirement Applicable to All Groups:

3. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differs in structure and in function and in biological activity. A restriction is applied to each Group. For an elected Group drawn to kits containing primer pairs and probes for α1 and α2 nucleotide sequences, the Applicants must elect a single primer pair and a single probe corresponding to the amplified region produced by the elected primer pair for each of the α1 and α2 sequences. Additionally, for an elected Group drawn to kits containing antibodies for α1 and α2 subunit detection, applicant must elect a single antibody for the detection of the α1 subunit and a single antibody for the detection of the α2 subunits.

For example, if Group I is elected, any one of the listed primer pairs specific for α1 in claim 50 and a single probe corresponding to the amplified region of the elected primer pair in claim 50, ie. a single probe to SEQ ID NO:1(claims 53 and 55), will be examined. In addition, any one of the listed primer pairs specific for α2 in claim 51 and a single probe corresponding to the amplified region of the elected primer pair of claim 51, ie. a single probe for SEQ ID NO:3(claims 54 and 56), will be examined.

In total, the election of Group I will include the applicant's further election of 6 sequences(1 primer pair for each α1 and α2, and 2 probes for each α1 and α2). If Group II is elected, applicant will need to further elect 2 antibodies one capable of detecting the α1 subunit and the other the α2 subunit.

The search of the selected sequences may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. Similarly, proteins comprising unique amino acid sequences are structurally and functionally distinct. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

4. Because these inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, examination of these inventions lacking the same special technical feature would pose a serious burden on the examiner and therefore the lack of unity requirement and subsequent election of desired Group for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Friday from 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W.Gary Jones, can be reached on (703)308-1152. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantai Dessau whose telephone number is (703)605-1237.

Sally Sakelaris
8/26/02

CARLA J. MYERS
PRIMARY EXAMINER